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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,153	01/13/2004	Leslie S. Johnson	13783-105015US1	2042

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
11/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/756,153	JOHNSON ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *1,2,7,9-22,24-48,50-55,59 and 60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6,8,23,49 and 56-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/5/07, 8/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence alignment*.

DETAILED ACTION

1. Applicant's response received August 27, 2008 is acknowledged.

Claims 1-60 are pending in the instant application.

Applicant's elections of Group I, drawn to fusion proteins, and the species of SEQ ID NO:42 as a specific fusion protein which comprises $Fc_{\gamma}RIIB$, in the reply filed on August 27, 2008 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 2, 7, 9-22, 24-48, 50-55, 59, and 60 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 27, 2008 as explained above.

Claims 3-6, 8, 23, 49, and 56-58 are under examination in this office action.

Information Disclosure Statement

2. The IDS forms received 10/5/07 and 8/28/08 are acknowledged. The first page of the 10/05/07 IDS has been lined through because it does not contain any cited references.

Specification

3. The title and abstract are objected to for not clearly indicating the subject matter that is being examined in this instant application. Specific mention of $Fc_{\gamma}RIIB$ is suggested as part of an appropriate amendment to overcome this objection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-6, 23, 49, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed fusion polypeptides which do not bind any FcγR. The specification discloses that the term FcγR is generic and collectively encompasses CD16 (FcγRIII) CD32 (FcγRII) and CD64 (FcγRI) (see particularly pages 1-3, Table 1, and Table 1). The specification further discloses that the human IgG2 constant region was chosen for the fusion proteins described in the working examples because FcγR does not bind to this constant region (see the first paragraph of example 6.1 starting on page 105). However, it is known in the art that human IgG2 binds quite well to FcγR (Presta et al., US Patent 6,911,321, see entire document, particularly examples 3-7, most particularly example 5). Given that Fcγ receptors physiological role is to bind IgG molecules, it does not appear reasonable that the claimed molecules would demonstrate 0% binding to any FcγR from any species. This problem is exacerbated since the Fc domain can come from any species and in the broadest claim the FcRn binding moiety does not even need to be an immunoglobulin Fc domain. Further, it appears that even the working example of SEQ ID NO:42 does not meet the limitations recited in the instant claims concerning the lack of binding to Fcγ receptors since cynomolgus monkey FcγRIIB binds human IgG2 quite well (see particularly example 5 of Presta et al.).

Therefore, based upon the breadth of the claimed invention, the guidance and working examples of the specification, and the teachings of the art, it does not appear that a skilled artisan could make and use the invention as presently claimed without first conducting additional unpredictable experimentation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Maddon et al. (US Patent 6,034,223).

Maddon et al. disclose fusion proteins comprising IgG2 (see entire document). The instant claim recites "an isolated polypeptide comprising an amino acid sequence of one of…". The use of the indefinite article in reference to sequences identified by SEQ ID number, indicates that the claims encompass a polypeptide comprising the entirety of a given SEQ ID number, as well as fragments of said SEQ ID number. As evidenced by the enclosed sequence alignment, the fusion protein of Maddon et al. comprises a fragment of SEQ ID NO:42.

Therefore, the prior art anticipates the claimed invention.

8. Claims 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Sondermann et al. (WO 00/32767, of record as B9 on the 8/28/08 IDS).

Sondermann et al. disclose soluble forms of human $Fc_{\gamma}RIIB$ (see entire document, particularly example 1 beginning on page 17). Note that the fusion protein of SEQ ID NO:42 comprises the extracellular domain of human $Fc_{\gamma}RIIB$ fused to IgG2. The claims recite an indefinite article in relation to the recited SEQ ID numbers, and

thus the scope of the claims encompasses fragments of the recited SEQ ID numbers. The polypeptides of Sondermann et al. thus comprise a fragment of SEQ ID NO:42. Note that $Fc_{\gamma}RIIB$ binds immunoglobulins, and thus the polypeptides of Sondermann et al. bind immune complexes.

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 8, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Presta et al. (US Patent 6,911,321) in view of Allaway et al. (US Patent 5,817,767).

Presta et al. disclose fusion polypeptides comprising $Fc_{\gamma}RIIB$ joined to the Fc portion of an immunoglobulin (see entire document, particularly lines 50-60 of column 4, columns 9 and 10, columns 23-25, and column 71). This disclosure differs form the instant invention in that Presta et al. do not disclose that the immunoglobulin isotype is to be IgG2.

Allaway et al. disclose that fusion constructs wherein a heterologous molecule is joined to IgG2 enjoys the advantages of reduced potential immunogenicity since there is

minimal allotypic variation in human IgG2 as compared to other isotypes (see entire document, particularly lines 60-67 of column 2).

Therefore, the fusion polypeptides of the instant claimed invention would have been obvious to a person of ordinary skill in the art at the time the invention was made. A person of ordinary skill in the art would have been motivated to make the fusion constructs of Presta et al. using an IgG2 isotype to gain the advantage of reduced immunogenicity as disclosed by Allaway et al.

11. Claims 8, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sondermann et al. (WO 00/32767, of record as B9 on the 8/28/08 IDS) in view of Ashkenazi et al. (Curr Opin Immunol, 1997, 9:195-200) and in view of Allaway et al. (US Patent 5,817,767).

Sondermann et al. disclose soluble forms of human Fc_{γ}RIIB (see entire document, particularly example 1 beginning on page 17). It is further disclosed that these soluble forms are to be administered in pharmaceutical compositions to patients (see particularly pages 8-9). This disclosure differs from the claimed in that fusion proteins comprising Fc_{γ}RIIB joined to IgG2 are not disclosed.

Ashkenazi et al. discloses that the administration of soluble therapeutic polypeptides as fusion molecules with the Fc domain of an immunoglobulin (aka immunoadhesins) enjoy the advantage of increased in vivo half-life as compared to the starting therapeutic polypeptide, and that such molecules have a further advantage of being easy to purify due to the Fc domain (see entire document, particularly the right column of page 195 and the left column of page 196). It is further disclosed that any human Fc domain can be used to make an immunoadhesin, and that the presence of the Fc domain makes such molecules dimeric (ibid. and Figure 1).

Allaway et al. disclose that fusion constructs wherein a heterologous molecule is joined to IgG2 enjoys the advantages of reduced potential immunogenicity since there is minimal allotypic variation in human IgG2 as compared to other isotypes (see entire document, particularly lines 60-67 of column 2).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the soluble $Fc_{\gamma}RIIB$ molecules of Sondermann et al. into immunoadhesins to gain the advantages of increased in vivo half-life and ease of purification as disclosed by Ashkenazi et al. A person of ordinary skill in the art would have been further motivated to select IgG2 as the isotype to be used in the immunoadhesin since immunoadhesins comprising IgG2 are less immunogenic than other human isotypes as was disclosed by Allaway et al.

Claim Objections

12. Claim 49 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 23. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Note that in the instant case the claims are identically worded. Cancellation of one of the claims is suggested.

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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